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09/661,773	09/14/2000	Simon F. Williams	TEPH 102	1585

23579 7590 06/18/2003

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EXAMINER

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/18/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 16

Application Number: 09/661,773
Filing Date: September 14, 2000
Appellant(s): WILLIAMS ET AL.

Zhaoyang Li
For Appellant

MAILED
JUN 18 2003
GROUP 2900

EXAMINER'S ANSWER

This is in response to the appeal brief filed 04/11/03.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

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(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims, 1-17, 29-32 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

6,277,413

Sankaram

08-2001

(10) *Grounds of Rejection*

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The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-17, 29-32 are rejected under 35 U.S.C. 102(b). This rejection is set forth in prior Office Action, Paper No. 8.

(11) *Response to Argument*

Appellant correctly argues that Sankaram discloses a pharmaceutical composition having microspheres which include both polymer and lipid components for use in drug delivery. These lipid components are not excluded from the instant claims since appellant merely claims a fluid comprising polyhydroxyalkanoate. Further, appellant argues that there is no disclosure of a composition which "imparts to the fluid composition properties so as to make it suitable for the repair or augmentation of tissue in an animal or human". Review of the independent claims, shows that claim 1 recites in broad terms a polyhydroxyalkanoate composition which is injectable. The intended use for repair of tissue is not given patentable weight since appellant is not claiming a method of repairing tissue but a composition. As such, the composition is clearly disclosed by Sankaram, regardless of its intended use.

It is further agreed that the legal standard for an anticipation rejection under 36 USC 102(b) requires the examiner to ascertain that each and every element of a claim is found, either expressly or inherently described in a single prior art reference.

Verdegaal Bros V. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed Cir. 1987). Contrary to appellant's assertion, the prior art does disclose the

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subject matter of the independent as well as dependent claims. This examiner will endeavor to provide arguments to that effect in the following paragraphs.

Appellants argue that the material claimed must have a certain set of chemical, physical, mechanical and biological properties in order to make it suitable for soft tissue repair and augmentation. A review of independent claims 1 and 29 will show that these specific characteristics are not set out in those claims. While Sankaram does not set out the use of such a composition for tissue repair or augmentation, appellant is again reminded that this is an intended use of the claimed composition. Claims 1 and 29 merely set out a biocompatible, bioabsorbable, fluid composition of polyhydroxyalkanoate. (See Abstract of Sankaram for reference to aqueous suspension).

Appellants further argue that since the Sankaram reference contains a substantial amount of lipid, it would be unsuitable for use in soft tissue repair and construction. As above, appellants are reminded that intended use of a composition does determine patentability of that composition. Further, there is no limitation of the composition which would exclude lipids or any other compound given that the claims use the open ended language "comprising" when setting out their polyhydroxyalkanoate composition. As evidence of the intention to include other ingredients, the Board should note the appellants statement in the instant application at page 11, in the first paragraph under 'Other Agents'. Appellant states that other agents may be added to

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increase the efficacy or safety of the composition. Lipids are specifically recited for addition to the claimed polyhydroxyalkanoate composition at the last sentence of that same paragraph. Therefore, the Sankaram does indeed anticipate the claims under 35 US 102.

Appellant points to the amendment of the claims introducing which specifically point out that the composition is variously, a bulking agent, viscosupplement, suitable for use in soft tissue repair and augmentation, and lastly suitable for use as viscosupplements. However, these are again considered intended uses of a composition clearly disclosed by the prior art.

It is noted that appellant does not argue as why the specific properties set out in the dependent claims are also anticipated. For the sake of completeness however, these will be quickly discussed.

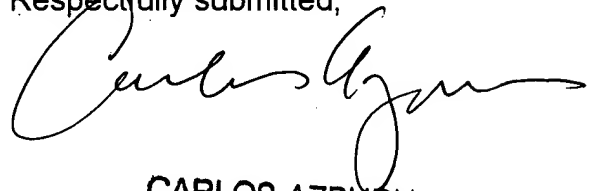
With regard to an injectable liquid Sankaram discloses just such a formulation at col3, lines 54-57; col. 9, lines 35-37; col. 10, lines 62-67. Viscosity characteristics are therefore inherently within the ranges claimed since the ordinary practitioner would not be able to inject the therapeutic composition if the viscosity were not within the claimed limits. Biodegradable polymers and polyhydroxyalkanoate in particular are discussed at col. 3, lines 4-6. Molecular weight range is disclosed at col. 7, lines 22-24. particle size is

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found at col. 12, line 65, and col. 17, line 52. It is therefore felt that Sankaram anticipates both the independent and independent claims of the instant application.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



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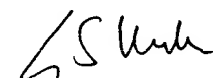
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June 12, 2003

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